

UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF OHIO
EASTERN DIVISION

IN RE: NATIONAL PRESCRIPTION)	CASE NO. 1:17-MD-2804
OPIATE LITIGATION)	
)	JUDGE POLSTER
THIS DOCUMENT RELATES TO:)	
<i>“Track Three Cases”</i>)	
)	
)	<u>ORDER DENYING MOTION</u>
)	<u>FOR RECONSIDERATION</u>
)	<u>OR CERTIFICATION</u>

On August 6, 2020, the Court entered an Order denying the Pharmacy Defendants’ Motion to Dismiss Plaintiffs’ Second Amended Complaints in the Track Three Cases. *See* docket no. 3403 (*“Track Three Order”*). The Pharmacy Defendants now ask the Court to either: (1) reconsider and grant their motion to dismiss; or (2) certify the *Track Three Order* for interlocutory appeal to the Sixth Circuit (on federal law questions) and to the Ohio Supreme Court (on state law questions).

For the reasons below, the Court issues a clarification of the *Track Three Order*. But the motion for reconsideration is otherwise **DENIED** and the motion for certification is also **DENIED**.

I. Background.

With their original motion to dismiss, the Pharmacy Defendants advanced four arguments, all of which the Court rejected. These arguments were: (1) Plaintiffs’ common law absolute public nuisance claims are abrogated by Ohio statutes; (2) the Pharmacy Defendants (as opposed to their

pharmacist-employees) have no duty under the Controlled Substances Act to prevent diversion of opioids via illegitimate prescriptions; (3) a claim for public nuisance predicated on a pharmacy's *dispensing* activity (as opposed to *distribution* activity) is not cognizable under Ohio law; and (4) the learned intermediary doctrine breaks the causal chain between the Pharmacy Defendants' conduct and Plaintiffs' alleged injuries.

With the instant motion, the Pharmacy Defendants ask the Court to reconsider "two of its conclusions" – the first and second listed above. Motion at 2. Specifically, Defendants insist the Court "erred [when analyzing Defendants' abrogation argument] by applying *State ex rel. Morris v. Sullivan*, 90 N.E.2d 146 (Ohio 1909), to conclude that Ohio Rev. Code §4729.35 does not preclude Plaintiffs' public nuisance claim." Motion at 19 (citing *Track Three Order* at 5-7). Regarding the Court's analysis of the Controlled Substances Act, Defendants maintain the Court erred when it "concluded that pharmacy registrants have a 'corporate-level obligation to design and implement systems, policies, or procedures to identify red flag prescriptions.'" *Id.* at 2 (quoting *Track Three Order* at 25).

II. Legal Standard for Reconsideration.

"Traditionally, courts will find justification for reconsidering interlocutory orders [only] when there is . . . a need to correct a clear error or prevent manifest injustice." *Rodriguez v. Tenn. Laborers Health & Welfare Fund*, 89 Fed. Appx. 949, 959 (6th Cir. 2004). "Motions for reconsideration are disfavored, and a motion for reconsideration is unfounded unless it either calls . . . attention to an argument or controlling authority that was overlooked or disregarded in the original ruling, presents evidence or argument that could not previously have been submitted, or

successfully points out a manifest error of fact or law.” *Davie v. Mitchell*, 291 F.Supp.2d 573, 634 (N.D. Ohio 2003).

III. Defendants’ Argument Regarding Abrogation.

In their reconsideration motion, Defendants’ abrogation argument rests entirely on the premise that Ohio Rev. Code §4729.35 codifies common law public nuisance. Motion at 19-21. But Defendants do not raise any new argument nor cite any new controlling precedent that was not offered in the parties’ original briefing on the motion to dismiss. And Defendants’ assertion that the Court committed a manifest legal error by analyzing §4729.35 using the rule of construction announced in *Morris v. Sullivan*, rather than the rule in *Bolles v. Toledo Trust Co.*, 58 N.E.2d 381 (Ohio 1944), is not well-taken. The *Track Three Order* analyzed §4729.35 under both *Morris* and *Bolles* and found neither case supported Defendants’ contention that §4729.35 abrogated common law public nuisance causes of action or remedies. *See Track Three Order* at 5-9 (discussing *Morris*) and 9-12 (discussing *Bolles*). “The Defendants may disagree with the Court’s decision, but that is an issue for appeal, not reconsideration.” *W. Kentucky Royalty Tr. v. Armstrong Coal Reserves, Inc.*, 2013 WL 4500189, at *1 (W.D. Ky. Aug. 21, 2013).

The Pharmacy Defendants also request that, if reconsideration is not granted, the Court should “certify the question to the Ohio Supreme Court.” Motion at 23 (referring to the question of “[w]hether Ohio Rev. Code §4729.35 precludes an absolute public nuisance cause of action for abatement or damages based on an alleged violation of the controlled-substance laws”). But “[t]he appropriate time to seek certification of a state-law issue [to the Ohio Supreme Court] is *before* a District Court resolves the issue, not after receiving an unfavorable ruling.” *City of Columbus, Ohio*

v. Hotels.com, L.P., 693 F.3d 642, 654 (6th Cir. 2012) (emphasis added). *See also Sims Buick-GMC Truck, Inc. v. Gen. Motors LLC*, 876 F.3d 182, 190 (6th Cir. 2017) (“Certification is disfavored in any event when the party, as here, makes the request after the district court has already decided the issue against it.”); *In re National Prescription Opiate Litig.*, 2018 WL 5923704, at *1 (N.D. Ohio Nov. 13, 2018) (denying, as untimely, *Summit County Distributor Defendants’* motion for leave to certify questions to the Ohio Supreme Court “after receiving an unfavorable result in Magistrate Judge Ruiz’s R&R”).

Defendants’ passing reference to certification in a footnote contained in their reply brief, *see* docket no. 3379 at 2-3 n.3, does not qualify as a timely, serious, or useful request for certification. Accordingly, the motion for certification to the Ohio Supreme Court is also denied.

IV. Defendants’ Argument Regarding the Controlled Substances Act (“CSA”).

In their motion to dismiss, the Pharmacy Defendants contended that “the responsibility to guard against invalid prescriptions [imposed by the CSA] rests with individual pharmacists, and *only* with individual pharmacists.” Docket no. 3340-1 at 14 (emphasis in original). “In other words,” the Court explained, “the Pharmacy Defendants now ask the Court to conclude that the CSA, as a matter of law, does not impose any obligation on a pharmacy-registrant, itself, to identify or investigate dubious prescriptions prior to filling them.” *Track Three Order* at 14. *See also* docket no. 3340-1 at 16 n.6 (Defendants argued the CSA regulations “only impose[] requirements for in-store physical security controls and ha[ve] never been understood to require a ‘system’ for monitoring prescriptions and disclosing ‘suspicious orders of controlled substances.’”).

The Court overruled the Pharmacy Defendants’ principal contention, and the Court reaffirms

its conclusion here: “**all** registrants [including pharmacies] have an affirmative obligation to protect not only against diversion via theft but also other forms of diversion more broadly.” *Track Three Order* at 15 (emphasis in original). The Court remains firm in its rejection of the Pharmacy Defendants’ argument that “they are entitled to dismissal of Plaintiffs’ claims because **only** their pharmacist-employees – and not also they, themselves – have a duty under the Controlled Substances Act to prevent diversion of opioids via illegitimate prescriptions.” *Id.* at 13 (emphasis in original). *See also id.* at 21 (“[T]he Pharmacy Defendants have not shown that sole responsibility for their dispensing practices rests with their pharmacist-employees. Rather, the CSA makes clear that any person, which includes a pharmacy itself, who knowingly fills or allows to be filled an illegitimate prescription is in violation of the Act.”).

In section III.B.2 of the *Track Three Order*, titled “System Requirement,” the Court addressed a secondary question regarding whether “the CSA also imposes duties on the Pharmacy Defendants to maintain systems, policies, or procedures to identify prescriptions that bear indicia (‘red flags’) that the prescription is invalid, or that the prescribed drugs may be diverted for illegitimate use.” *Id.* at 21-22. The Court concluded “that the Pharmacy Defendants cannot collect data as required by the statute, employ a licensed pharmacist as required by the statute, identify red flags as required by Agency decisions, but then **do nothing** with their collected data and leave their pharmacist-employees with the sole responsibility to ensure only proper prescriptions are filled.” *Id.* at 25 (emphasis added). The Court reaffirms that conclusion as well. The CSA’s fundamental mandate that **every** pharmacy-registrant must “provide **effective controls and procedures** to guard against theft and diversion of controlled substances,” 21 C.F.R. §1301.71(a) (emphasis added), means a pharmacy cannot be deliberately ignorant or willfully blind regarding its own prescription

information.¹ The DEA has repeatedly reaffirmed this conclusion.²

The Court went on, however, to characterize what a pharmacy “system” to identify illegitimate prescriptions might look like, including the type of red flags it could look for (e.g., “pattern prescribing”), how it could look for them (e.g., using “computer algorithms”), and what it could do with the information it finds (e.g., “provide the pharmacist with data reports”). *Track Three Order* at 23. The Pharmacy Defendants object that this characterization goes too far: “[g]rafting an implicit data-analysis requirement” onto CSA regulations, where there is no explicit regulatory mandate, is “clearly erroneous.” Motion at 11. The Pharmacy Defendants further insist that neither the CSA nor its regulations require it *in any way* to “use their prescription records to

¹ In the motion for reconsideration, Pharmacy Defendants repeat their insistence that the meaning of “diversion” is limited to “theft” when describing the obligations of a pharmacy. *See* Motion at 12-13 (“the [CSA’s] security requirements [addressing theft] . . . [alone] are what is required to meet the ‘effective controls against diversion’ requirement”). The Court observes this assertion is undermined by the fact that pharmacy registrants must also keep certain records and employ a licensed pharmacist – requirements designed to help prevent diversion, but having little, if anything, to do with preventing theft. Thus, Pharmacy Defendants themselves acknowledge elsewhere in their same document that the meaning of “diversion” is *not* limited to “theft.” *See id.* at 14 (“Plaintiffs’ case is not about the many kinds of diversion that pharmacy-registrants are required to guard against, whether by protecting the physical security of their inventory or by employing licensed and reliable pharmacists.”).

² Pharmacy Defendants cite several cases, including *JM Pharmacy Group, Inc., d/b/a Farmacia Nueva and Best Pharma Corp; Decision and Order*, 80 FR 28667-01 (May 19, 2015), for the proposition that “not a single DEA opinion” holds that pharmacies have a duty to “conduct a computerized red-flag analysis before they allow their pharmacists to exercise their professional judgment to fill incoming prescriptions.” Motion at 15. As discussed below, the Court agrees the CSA does not *necessarily* require “a computerized red-flag analysis.” But *JM Pharmacy* and other DEA decisions make clear that: (1) a pharmacist may not engage in “deliberate ignorance or willful blindness” when assessing whether a prescription is illegitimate, *id.* at *28670; and (2) “[t]he corresponding responsibility to ensure the dispensing of valid prescriptions extends to the pharmacy itself,” *id.* at 28685 (quoting and citing numerous DEA decisions). *See id.* (“Settled [DEA] precedent . . . prohibit[s] the filling of a prescription where the pharmacist *or pharmacy* ‘knows or has reason to know’ that the prescription is invalid.”) (emphasis added).

monitor for questionable prescriptions.” *Id.* at 8 (capitalization changed, quotation marks omitted).

The Court agrees with Defendants that portions of its Opinion can be read as imputing specific requirements into the CSA that are not present in the text of the Act. This was not the Court’s intent. Despite any language in the *Track Three Order* that reads to the contrary, the Court was explicit that “the CSA is not perfectly clear about what a pharmacy-registrant must do with the prescription data it must collect.” *Track Three Order* at 24. Therefore, the Court now clarifies that the CSA and its regulations do not specify exactly what “effective controls and procedures” a pharmacy must use to prevent diversion of controlled substances. Thus, there is no absolute requirement, for example, that a pharmacy must conduct a computerized red-flag analysis of each prescription before filling it; the Court did not mean to so suggest in the *Track Three Order*. Similarly, Defendants are correct that there is no **explicit** requirement that they use the prescription data they collect to prevent diversion.

It remains true, however, that a pharmacy may not fill a prescription that it knows or has reason to know is invalid and may not remain deliberately ignorant or willfully blind of the prescription information it has (including computerized reports it generates). *JM Pharmacy Group, Inc., d/b/a Farmacia Nueva and Best Pharma Corp; Decision and Order*, 80 FR 28667-01 at *28670 (May 19, 2015); *Holiday CVS, L.L.C., d/b/a CVS/Pharmacy Nos. 219 and 5195; Decision and Order*, 77 FR 62316-01 at *62322 and *62322 n.26 (Oct. 12, 2012); *Medicine Shoppe – Jonesborough; Revocation of Registration*, 73 FR 364-01 at *381 (Jan. 2, 2008). To repeat: pharmacies may not “do nothing with their collected data and leave their pharmacist-employees with the sole responsibility to ensure only proper prescriptions are filled.” *Track Three Order* at 25. What the Pharmacies actually did, and whether it was sufficient, must await discovery and cannot

be determined on a motion to dismiss.

Finally, the Pharmacy Defendants request that, if reconsideration is not granted, the Court should certify the *Track Three Order* for interlocutory appeal to the Sixth Circuit. Motion at 21. Certifying appeal under §1292(b) is warranted “sparingly and only in exceptional cases.” *In re City of Memphis*, 293 F.3d 345, 351 (6th Cir. 2002). “[D]oubts regarding appealability [should be] resolved in favor of finding that the interlocutory order is not appealable.” *Adell v. Cellco P’ship*, 2019 WL 5285627, at *1 (N.D. Ohio Oct. 18, 2019) (quoting *United States v. Stone*, 53 F.3d 141, 143-44 (6th Cir. 1995)). Interlocutory appeal “is not warranted when a plaintiff asserts similar claims involving the same evidence as the claims that would be appealed, such that litigation will proceed in substantially the same manner even if the appeal results in dismissal of those claims.” *In re Nat’l Prescription Opiate Litig.*, 2020 WL 2128462, at *1 (N.D. Ohio May 5, 2020).

The Court declines Defendants’ request because it is not the case that “an immediate appeal [to the Sixth Circuit] from the [*Track Three Order*] may materially advance the ultimate termination of the litigation.” 28 U.S.C. §1292(b). This is true because: (1) Plaintiffs’ claims against the Pharmacy Defendants in their role as opioid *distributors*, as compared to opioid *dispensers*, are unaffected by the *Track Three Order*, so the litigation must proceed to trial in any event; (2) Plaintiffs’ public nuisance claim may be grounded in either unlawful *or* intentional conduct, and Defendants’ motion seeks reconsideration of only the unlawful conduct prong; (3) the Court’s clarification in this Order largely (if not entirely) addresses Defendants’ asserted need for interlocutory appellate review; (4) whether Defendants undertook “effective controls and procedures” to prevent diversion is not a “pure question of law,” *Kollaritsch v. Michigan State Univ. Bd. of Trustees*, 944 F.3d 613, 624 (6th Cir. 2019); and (5) to the extent appellate review of any

remaining questions raised in the motion for reconsideration is necessary, it would best be done on a full factual record.

IT IS SO ORDERED.

/s/ Dan Aaron Polster

**DAN AARON POLSTER
UNITED STATES DISTRICT JUDGE**

Dated: September 22, 2020